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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,644	09/27/2001	Mark W. Bitensky	S-092701	3052

7590 09/05/2003

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EXAMINER

SPIEGLER, ALEXANDER H

ART UNIT

PAPER NUMBER

1637

10

DATE MAILED: 09/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/965,644	BITENSKY ET AL.
	Examiner Alexander H. Spiegler	Art Unit 1637

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 10 April 2003.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-46 is/are pending in the application.

4a) Of the above claim(s) 19-46 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-18 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election of Group I (claims 1-18) in Paper No. 8, filed on April 10, 2003, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 19-46 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.
3. Claims 1-18 have been examined on the merits and are rejected.

***Information Disclosure Statement***

4. The information disclosure statement of Paper No. 5 complies with CFR 1.97, 1.98, and M.P.E.P. 609, and has been considered (see enclosed signed PTO-1449).

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, Claim 17 is indefinite over "said microchannels have dimensions on the same scale as human capillaries" because it is not clear as to what encompasses what dimensions

are considered to be "on the same scale of human capillaries. That is, the metes and bounds of what encompasses "the same scale as human capillaries" are unclear.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Sutton et al. (Microvascular Research (1997) 53: 272-281).

Regarding Claim 1, Sutton teaches an array comprising a plurality of microchannels for capturing an individual cell (see abstract, pg. 274 and Fig. 6, for example).

Regarding Claim 2, Sutton teaches the array comprises at least a first and a second set of microchannels (both having cross sectional areas), wherein said first cross sectional area is larger than said second cross sectional area, and wherein said microchannels form a gradient for capturing said cell (see Fig. 1 and pg. 278, for example) (teaching differing width lengths for the microchannels, thus teaching an array having one larger and one smaller cross-sectional area).

Regarding Claims 3-8, 12-14 and 18, Sutton teaches "substantially wedge-shaped" microchannels having a depth of 3.2 um, a width of between 3-4 um, and a length of 100 um (see pg. 278, column 1, for example) (the entry and exit portions are inherent to Sutton's microchannels). Furthermore, absent a specific definition of "about", the dimensions taught by Sutton are considered to encompass the dimensions of the microchannels claimed in Claims 5-8. Likewise, with respect to Claim 18, Sutton teaches a plurality of sets of microchannels having

dimensions that are encompassed by the recitation of "about" (see Figs. 1, 6 and pg. 278, for example).

Regarding Claims 9-10, Sutton teaches the microchannels are adapted to prevent a cell from escaping from said microchannels and that the microchannels have a width of between "about" 1.5 to "about" 0.5 microns and a length of between "about" 0.5 to "about" 30 microns (pgs. 274-276, for example).

Regarding Claims 11 and 15-16, Sutton teaches that said microchannels are adapted to maintain a constant rate of fluid flow therethrough and that Sutton's array further comprises a means of moving cells through the microchannels (e.g., negative pressure by connected water columns (pgs. 275-276 and 278, for example).

Regarding Claim 17, Sutton teaches that the microchannels are used to simulate the dimensions of human capillaries (see title and abstract, for example).

9. Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Brody et al. (Biophysical J. (1995) 68(6) 2224-2232).

Regarding Claim 1, Brody teaches an array comprising a plurality of microchannels for capturing an individual cell (see abstract, pgs. 2224-2225 and Figs. 1-4, for example).

Regarding Claim 2, Brody teaches the array comprises at least a first and a second set of microchannels (both having cross sectional areas), wherein said first cross sectional area is larger than said second cross sectional area, and wherein said microchannels form a gradient for capturing said cell (see pgs. 2225-2226 and Figs. 1-4, for example) (teaching differing width

lengths for the microchannels, thus teaching an array having one larger and one smaller cross-sectional area).

Regarding Claims 3-8, 12-14 and 18, Brody teaches “substantially wedge-shaped” microchannels having a depth of 4 um, a width of between 2.5 to 4 um, and a length of 12, 13 or 20 um (see pgs. 2225-2227 and Figs. 1-4, for example) (the entry and exit portions are inherent to Brody’s microchannels). Furthermore, absent a specific definition of “about”, the dimensions taught by Brody are considered to encompass the dimensions of the microchannels claimed in Claims 5-8. Likewise, with respect to Claim 18, Brody teaches a plurality of sets of microchannels having dimensions that are encompassed by the recitation of “about” (see pgs. 2225-2227 and Figs. 1-4, for example).

Regarding Claims 9-10, Brody teaches the microchannels are adapted to prevent a cell from escaping from said microchannels and that the microchannels have a width of between “about” 1.5 to “about” 0.5 microns and a length of between “about” 0.5 to “about 30 microns (pgs. 2226-2227, for example).

Regarding Claims 11 and 15-16, Brody teaches that said microchannels are adapted to maintain a constant rate of fluid flow therethrough and that Brody’s array further comprises a means of moving cells through the microchannels (e.g., negative pressure by connected water columns (pgs. 2226-2227, for example).

Regarding Claim 17, Brody teaches that the microchannels are used to simulate the dimensions of human capillaries (see pg. 2224, for example).

### ***Conclusion***

10. No claims are allowable.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (703) 308-2199. If attempts to reach Carla Myers are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*Alexander H. Spiegler*  
Alexander H. Spiegler  
September 2, 2003

*Carla Myers*  
CARLA J. MYERS  
PRIMARY EXAMINER